MAY 1 8 2000

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K000611.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Biometric Imaging, Inc.*
1025 Terra Bella Avenue
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Summary date: February 22, 2000

Device Name/Classification (21 CFR 807.92(a)(2))

Name: STELLer® CD61 Assay for use on the IMAGN® 2000 Microvolume Fluorimeter

Classification: Class II (Regulation Code 864.5220)

Substantially Equivalent**/Predicate Device (21 CFR 807.92(a)(3))

The STELLer CD61 Assay is substantially equivalent to the Brecher and Cronkite platelet counting method for the enumeration of human platelets in peripheral blood between 1,000 and 50,000 platelets/μL.

*Biometric Imaging, Inc. (BMI) is a Becton Dickinson company.

** The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description (21 CFR 807.92(a)(4))

Biometric Imaging's (BMI) STELLer CD61 Assay is intended for use with the IMAGN® 2000 microvolume fluorimeter to determine the concentration of platelets in peripheral blood between 1,000 and 50,000 platelets/μL. The STELLer CD61 Assay Kit contains Cy5-labeled CD61 Reagent, CD61 Diluent, CD61 Calibrator, and volumetric capillaries, sufficient for 20 tests. The Diluent is used to prepare the samples for analysis. The Calibrator is used to measure and verify the instrument response to the fluorescent dye in the CD61 antibody reagent.

Intended Use (21 CFR 807.92(a)(5))

For in vitro diagnostic use to identify and enumerate accurate platelet counts in peripheral blood between 1,000 and 50,000 platelets/μL.

Technological Characteristics (21 CFR 807.92(a)(6))

The STELLer platelet assay uses a specific antibody that recognizes the CD61 surface glycoprotein receptor found almost exclusively on human platelets and megakaryoblasts.[1] The CD61 antibody (clone VI-PL2)[2] recognizes the gpIIIa antigen that is the common β-subunit (integrin β_3 chain) of the gpIIb/IIIa[2] complex found on platelets. This receptor mediates platelet adhesion and aggregation.[3]

The STELLer CD61 Assay is performed by mixing a sample and diluent with a reagent containing anti-human CD61 antibody conjugated to a fluorescent dye. Following a short incubation period, an aliquot of the diluted reaction mixture is pipetted into two volumetric capillaries inserted in a VC-2 cartridge. The cartridge is then loaded into the IMAGN 2000 instrument for analysis.

The instrument uses a laser light source (633 nm from a helium neon laser) to excite the fluorescent dye. The number of $CD61^+$ platelets/μL of a sample is automatically reported.

1. Wong DA, Springer TA. CD61 (b3) cluster report. In: Schlossman SF, Boumsell L, Gilks W, et al, eds. *Leukocyte Typing V, White Cell Differentiation Antigens*. Oxford: Oxford University press; 1995:1664-1665.
2. Modderman PW. Cluster report: CD61. In: Knapp W, Dörken B, Gilks WR, et al, eds. *Leukocyte Typing IV: White Cell Differentiation Antigens*. New York, NY: Oxford University Press; 1989:1025.
3. Favier R, Morel MC, Potevin F, Kaplan C, Lecompte T. The glycoprotein complex gpIIb/IIIa contains very distinct epitopes and may be associated with the CD9 molecule within the platelet plasma membrane. In: Knapp W, Dörken B, Gilks WR, et al, eds. *Leukocyte Typing IV: White Cell Differentiation Antigens*. New York, NY: Oxford University Press; 1989:1006-1008.

In contrast, the Brecher and Cronkite platelet counting procedure requires manual counts of platelets in a fixed volume hemacytometer with a phase contrast microscope after red cell hemolysis and dilution.

The STELLer CD61 Assay provides equivalent platelet counts to the Brecher and Cronkite platelet counting procedure.

Performance Data (21 CFR 807.92(b)(1) and (2))

Performance of the product was established by testing at Memorial Sloan Kettering Cancer Center, New York, New York; University of Washington Hospital, Seattle, Washington; and Biometric Imaging, Mountain View, California. All samples used in the following studies were obtained from excess material drawn for other purposes.

Several studies were performed:

- Accuracy was determined by comparing results from peripheral blood specimens prepared with the STELLer CD61 Assay on the IMAGN 2000 to the Brecher and Cronkite platelet counting procedure. A total of 167 specimens were used for the evaluation and analyzed from three clinical sites. Data demonstrated that the STELLer CD61 Assay is equivalent to the predicate.
- Within sample reproducibility was performed on 5 peripheral blood specimens with average platelet counts between 5,551.2 – 13,012.0 platelets/μL. Five replicates were prepared for each sample and run once on the IMAGN 2000. Results demonstrated acceptable within-sample reproducibility with CVs of $< 10\%$.
- Across instrument reproducibility was performed on one whole blood sample with a normal platelet count diluted to three platelet concentrations (low, medium, and high) to span the reportable range of the system. Three dilutions were assayed on five instruments. Results demonstrated acceptable across instrument reproducibility.
- Across day reproducibility was performed on two levels of stabilized platelet samples, one at 4,000 platelets/μL and the other at 40,000 platelets/μL, over ten days at BMI. Five replicates of each level were run each day. Results demonstrated acceptable reproducibility for absolute counts of CD61 positive platelets.
- Whole blood stability studies were conducted at one site using 25 samples. The studies assessed changes associated with the storage of peripheral blood at room temperature prior to staining and data acquisition. Results demonstrated acceptable stability of samples prepared up to 24 hours after blood draw.

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- Linearity was determined using a peripheral blood specimen with a normal platelet count diluted to 5 different concentrations that extended beyond the assay linear range of 1,000 to 50,000 platelets/μL. Results indicated a linear response over the range tested.
- An interfering substance study was conducted to validate that lipemic samples could be used in the STELLer CD61 Assay without impacting performance. Interference from lipemia was tested by fortifying five different samples with Liposyn® II, a synthetic lipid emulsion manufactured by Abbot Laboratories, at three different concentrations. Measured triglyceride concentrations after fortification ranged from 538.8 to 2593.2 mg/dL. Results demonstrated that whole blood samples with triglyceride concentrations across this range can be run with the STELLer CD61 Assay.

Conclusions from Performance Data (21 CFR 807.92(b)(3))

The results of the clinical studies demonstrate that the device is as safe and effective as the predicate device. The STELLer CD61 Assay is substantially equivalent to the Brecher and Cronkite platelet counting procedure in that they share the same intended use. Results demonstrate that the STELLer CD61 Assay yields equivalent platelet counts to the Brecher and Cronkite platelet counting procedure.

J. Peterson for
Nancy E. Isaac

Dec. 22, 2000

Nancy E. Isaac
Vice President – Regulatory Affairs
Becton Dickinson Biosciences

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2000

Ms. Jo-Ann E. Fabila, RAC
Regulatory Affairs
Becton Dickinson Biosciences
2350 Qume Drive
San Jose, California 95131

Re: K000611
Trade Name: STELLer® CD61 Assay for use on the IMAGN® 2000 Microvolume Fluorimeter
Regulatory Class: II
Product Code: GKZ
Dated: April 27, 2000
Received: April 28, 2000

Dear Ms. Fabila:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K000611

Device Name: STELLer® CD61 Assay

Indications For Use:

- For in vitro diagnostic use with the IMAGN® 2000 Microvolume Fluorimeter to identify and enumerate accurate platelet counts in peripheral blood between 1,000 and 50,000 platelets/μL.
- For in vitro diagnostic use.
- CD61 assay may be useful to monitor prophylactic and therapeutic platelet transfusions in patient thrombocytopenia due to quantitative platelet disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maher

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000611

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR § 801.109)